

copy of the supporting statement for this information collection is available on the Internet at "http://www.fda.gov/ohrms/dockets".

Dated: February 23, 1999.

William K. Hubbard,  
Acting Deputy Commissioner for Policy.  
[FR Doc. 99-5030 Filed 3-1-99; 8:45 am]

BILLING CODE 4160-01-F

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. 98E-0839]

##### Determination of Regulatory Review Period for Purposes of Patent Extension; Atacand

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for Atacand and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

**ADDRESSES:** Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**  
Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6620.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical

investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Atacand (candesartan cilexetil). Atacand is indicated for the treatment of hypertension. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Atacand (U.S. Patent No. 5,196,444) from Takeda Chemical Industries Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 16, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Atacand represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Atacand is 1,087 days. Of this time, 686 days occurred during the testing phase of the regulatory review period, while 401 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective:* June 15, 1995. The applicant claims May 16, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 15, 1995, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act:* April 30, 1997. FDA has verified the applicant's claim that the new drug application (NDA) for

Atacand (NDA 20,838) was initially submitted on April 30, 1997.

3. *The date the application was approved:* June 4, 1998. FDA has verified the applicant's claim that NDA 20,838 was approved on June 4, 1998.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 413 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before May 3, 1999, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before August 30, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the [docket number found in brackets in the heading of this document]. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 16, 1999.

Thomas J. McGinnis,  
Deputy Associate Commissioner for Health Affairs.

[FR Doc. 99-5032 Filed 3-1-99; 8:45 am]

BILLING CODE 4160-01-F

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Health Care Financing Administration

[Document Identifier: HCFA-R-228]

##### Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the



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a professional corporation

PSD

August 3, 1999

DIRECT NUMBER: 405/272-1915  
E-MAIL: OCONNELLS@MCKINNEYSTRINGER.COM  
REPLY TO OKLAHOMA CITY OFFICE

PATENT  
Att'y Dkt. No. 84660-0045

Commissioner for Patents and Trademarks  
Washington, D.C. 20231

07224550

Re:   Applicant:   Patrick H. Flores  
      Patent No.:   Des. 318,039  
      Issue Date:   July 9, 1991  
      For:            VEHICLE RUNNING BOARD

1999 AUG 11 PM 2:44  
DSD/PTCS  
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Transmitted herewith is a Change of Attorney's Address In Patent ~~in~~ the  
above-referenced patent, and a pre-addressed postal card.

The Commissioner is hereby authorized to charge any additional fees which may  
be required, or credit any overpayment, to Deposit Account No. 13-2493.

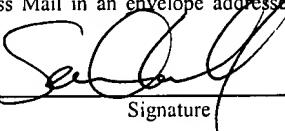
  
SEAN V. O'CONNELL, Reg. No. 42,951  
McKINNEY & STRINGER, P.C.  
Corporate Tower  
101 North Robinson, Suite 1300  
Oklahoma City, Oklahoma 73102-5504  
Phone: 405/272-1915  
Fax: 405/239-7902

SVO/tds/358258

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited on August 3, 1999, with the United States  
Postal Service with sufficient postage as First Class Mail in an envelope addressed to the Commissioner of Patents and  
Trademarks, Washington, D.C. 20231.

Sean V. O'Connell  
Name of Applicant, assignee or  
registered representative

  
Signature

August 3, 1999  
Date



DSD  
McKinney  
&Stringer  
a professional corporation

August 3, 1999

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E-MAIL: OCONNELL@MCKINNEYSTRINGER.COM  
REPLY TO OKLAHOMA CITY OFFICE

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fax 405.239.7902

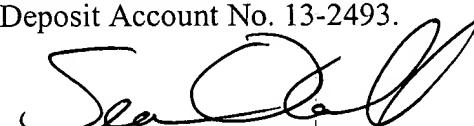
Mid-Continent Tower  
401 South Boston  
Suite 2100  
Tulsa, OK 74103  
918.582.3176  
fax 918.582.1403

Commissioner for Patents and Trademarks  
Washington, D.C. 20231

Re: Applicants: Andrew G. Butler and Ronald Wisnia  
Patent No.: Des. 308,644  
Issue Date: June 19, 1990  
For: CARPENTER LEVEL

Transmitted herewith is a Change of Attorney's Address In Patent in the above-referenced patent, and a pre-addressed postal card.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 13-2493.

  
SEAN V. O'CONNELL, Reg. No. 42,951

McKINNEY & STRINGER, P.C.

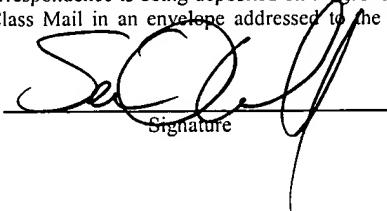
Corporate Tower  
101 North Robinson, Suite 1300  
Oklahoma City, Oklahoma 73102-5504  
Phone: 405/272-1915  
Fax: 405/239-7902

SVO/tds/358253

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Sean V. O'Connell  
Name of Applicant, assignee or  
registered representative

  
Signature

August 3, 1999  
Date

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DSD/PTCS  
RECEIVED



DESIGN  UTILITY  PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Patrick H. Flores

Patent No.: Des. 318,039

Examiner: James M. Gandy

Issue Date: July 9, 1991

Att'y Dkt.: 084660-0045

For: VEHICLE RUNNING BOARD

Commissioner for Patents and Trademarks  
Washington, D.C. 20231

**CHANGE OF ATTORNEY'S ADDRESS IN PATENT**

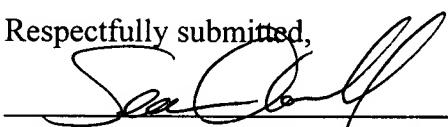
Effective immediately, please send all correspondence for this patent as follows:

Sean V. O'Connell, Reg. No. 42,951  
McKINNEY & STRINGER, P.C.  
Corporate Tower  
101 North Robinson, Suite 1300  
Oklahoma City, Oklahoma 73102-5504

Please direct telephone calls to:

Phone: (405) 272-1915  
Fax: (405) 239-7902

Respectfully submitted,

  
SEAN V. O'CONNELL, Reg. No. 42,951  
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Attorney for Applicant

**CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8**

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Sean V. O'Connell

Name of Applicant, assignee or  
registered representative

  
Signature

August 3, 1999

Date

12-09-98

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UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. no. 07/543,153

Filed: 19900625

Patent no.: D320,454

Issued: 19911001

Customer number: 21121



REQUEST TO CORRECT ATTORNEY DOCKET NUMBER IN PALM SYSTEM

The attorney docket number in the Palm system for the above-referenced file is incorrect. It is supposed to be:

PROPD002US

It is respectfully requested that this attorney docket number be corrected in the Palm system.

Carl Oppedahl  
Carl Oppedahl  
PTO Reg. No. 32,746  
Oppedahl & Larson LLP  
P O Box 5270  
Frisco, CO 80443-5270  
email: oppedahl@patents.com

12-09-99

DSR

UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. no. 07/371,663

Filed:

Patent no.: Re 33,528

Issued:

Customer number: 21121



**REQUEST TO CORRECT ATTORNEY DOCKET NUMBER IN PALM SYSTEM**

The attorney docket number in the Palm system for the above-referenced file is incorrect. It is supposed to be:

US

DOTY 003US

It is respectfully requested that this attorney docket number be corrected in the Palm system.

*Carl Oppedahl*

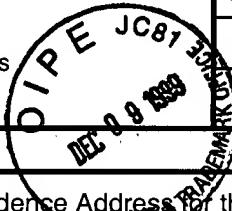
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**CHANGE OF  
CORRESPONDENCE ADDRESS  
Patent**

Address to:  
Assistant Commissioner for Patents  
Washington, D.C. 20231



Patent Number	5,779,859
Issue Date	July 14, 1998
Application Number	08/766260
Filing Date	December 13, 1996
First Named Inventor	Carter

Please change the Correspondence Address for the above-identified patent to:

Customer Number

OR

*Type Customer Number here*



Firm or Individual Name	Christopher W. Brody		
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Address	1750 K Street, NW, Suite 600		
City	Washington	State	DC
Country	USA		
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I am the :

- Pattee.
- Assignee of record of the entire interest.  
Certificate under 37 CFR 3.73(b) is enclosed.
- Attorney or agent of record .

Typed or Printed Name	Christopher W. Brody	Reg. No. 33,613
Signature		
Date	December 10, 1999	

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